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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,692	03/11/2005	Haruo Sugiyama	283121US0 PCT	7303

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
YOUNG, HUGH PARKER	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,692	SUGIYAMA, HARUO	
	Examiner	Art Unit	
	Hugh P. Young	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/9/2006, 12/29/2005, 7/27/2005, 3/11/2005.

DETAILED ACTION

This is the first Office action on the merits of application No. 10,527,692. There are seven claims pending, all of which are under consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gaiger et al, US Patent Application Publication US 2003/0082194 A1, published May 1, 2003 (filed February 22, 2001, claiming priority to US Provisional application No. 60/184,070).

3. Gaiger et al teach and claim a nonapeptide of amino acid sequence CMTWNQMNL (the instant SEQ ID NO:2) as their sequence, recited as two different SEQ ID NOS: 49 and 258 in the Gaiger '194 publication. Gaiger et al teach the nonapeptide CMTWNQMNL as part of a diagnosis and therapy derived from and related to Wilm's tumor antigen-associated cancers. They claim their peptide of SEQ ID NO: 49 in their claims 1,11, 23, 47 and 50, in the latter two claims, 47 and 50, as a member of small set (ten members) of peptides suitable for practicing the invention. In the body of the disclosure various properties of the peptide of SEQ ID NO: 49 are tabulated in Tables 4, 5, 6, 7, 17, 35, 38, 42 and 47, in paragraphs [0084, 0331, 0332, 0333, 0334, 0344, 0361, 0365, 0369 and 0374], respectively. The duplicate sequence, SEQ ID NO:

258, is similarly described in Tables 43 and 47, paragraphs [0370 and 0374], respectively. The two sequences are formally disclosed in the Sequence Listing, on page 85 (SEQ ID NO: 49) and page 115 (SEQ ID NO: 258). In paragraph [0228] Gaiger et al teach that their peptide formulations may be presented in single or multi-dose containers, as suspensions, solutions or emulsions in oily or aqueous vehicles. These methods of formulating medicaments are known in the pharmaceutical arts.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of cancer, does not reasonably provide enablement for prevention of a cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case Applicant discloses a peptide of SEQ ID NO: 2 (CMTWNQMNL) that is an antigen to peptides presented by cancer cells on their surfaces. By Applicant's definition, these cancer cells do not present the peptide moieties that identify them as cancer cells until the become cancerous, thus rendering any treatment of these cells by the peptide of the instant invention as, in fact and in practice, a post facto event, thus precluding any claim of prevention of cancer.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The factors follow:

1. *the nature of the invention*; claim 7 is drawn to a method for treatment of prevention of a cancer, comprising administering a peptide composition. The present rejection is directed towards the claim of prevention of a cancer.

2. *the breadth of the claims*; the instant claim 7 has a broad scope, being drawn to not only treatment of a certain type or class of cancer cells but to prevention of a cancer as well, specifically towards cancers in which the affected cells present particular, identifying peptide moieties on their surface.

3. *the predictability or unpredictability of the art*; in the instant case, Applicant's disclosure (page 3, line 20 et sequitur) that the cancers to be addressed by their invention derive from a gene on chromosome 11. The methods to be practiced using the instant invention are directed towards products of this gene (page 4 lines 14-22). Given that the gene is not active in non-cancerous cells, and is the defining genetic or physiological characteristics of these cancer cells, these cells are not detectable or treatable by the claimed method until they become cancerous and express the defective gene and its recognizable products. Whether or not a given cell will

become cancerous in not predictable, and cancerous cells are recognized by the compositions and methods of the instant invention only ex post facto, after they have become cancerous.

4. *the amount of direction or guidance presented*; Applicant provides three working examples of treatments administered to human subjects, all three of which are cancer patients who are already presenting tumors and the symptoms that accompany the cancers. No guidance is provided as to how to identify cells, or patients harboring cells, that are about to become cancerous. Applicant's disclosure recites only cancer cells and patients with cancers. The National Cancer Institute provides an overview of current progress (www.cancer.gov/cancertopics/pdq/prevention/overview/HealthProfessionl/) in cancer medicine. As indicated in this on-line publication, most methods of preventing cancer are directed towards eliminating or reducing exposure to carcinogens or lifestyles that induce cancers. The few chemoprentive practices discussed are similarly drawn to reducing a subject's hormonal or other host-specific predispositions towards increased vulnerability to carcinogens.

5. *the presence or absence of working examples*; the three working examples provided are drawn from treatment of human patients with active cancers, including leukemia. Thus all three examples are drawn to treatment, not prevention.

6. *the quantity of experimentation necessary*; given the lack of guidance or examples of how prevention would work, and in the light of the disclosure that the methods of the instant invention are, at the mechanistic level of the peptides and cells themselves, drawn entirely to

cells that have already become cancerous, it would require a large amount of research and experimentation to determine the predictive signs, if any, of cells or patients with cells, that are about to become cancerous.

7. *the state of the prior art;* and, the state of the prior art in regards cancer is that the broad array of medical conditions that comprise cancers are almost exclusively addressed by diagnosis and treatment, with efforts at preventing cancer being directed towards reduction or elimination of causes of mutations and tumor-promotion of mutated cells. Prevention efforts are thus directed towards reducing or eliminating exposure to carcinogenic chemicals, including "lifestyle" chemicals such as alcohol and tobacco products, as well as ionizing radiation, both solar and artificial.

8. *the relative skill of those skilled in the art;* In view of the discussion of each of the preceding seven factors the level of skill in this art is high and is at least that of a medical doctor or researcher with a doctoral degree in physiology, pharmacology, or related discipline, with several years of experience in the art. As the cited art would point to, even with a level of skill in the art, which is very high, predictability of the results is not invariable.

In consideration of each of factors 1 - 8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Conclusion

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hugh P. Young whose telephone number is (571)-272-4988. The examiner can normally be reached on 8:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hugh P. Young Ph.D. GAU 1654

Jon Weber
Supervisory Patent Examiner